K954564

Gammex

GAMMEX RMI®

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87(h).

1) SUBMITTER

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2) PRODUCT IDENTIFICATION

Brand Name:	PID-1 Precision Intelligent Dosimeter
Common Name:	Electrometer/Dosimeter
Classification Name:	Radiation Therapy Calibration Device

3) MARKETED DEVICES

Predicate Device:	Victoreen Model 530 Electrometer/Dosemeter (K931927)

4) DEVICE DESCRIPTION

The PID-1 Precision Intelligent Dosimeter is a battery-powered, stand-alone, precision electrometer for the calibration of medical radiation beams. It is designed to accommodate different types of ionization chambers and solid state detectors. The PID-1 also incorporates features for logging and transferring measured data to a host computer for analysis.

The PID-1 measures charge, charge rate (current), dose and dose rate. Time and date of measurement are automatically stored with the data. Temperature and pressure data can be entered for automatic correction of measurements.

5) INDICATIONS FOR USE

This device is intended to be used for precision measurement of ionizing radiation beams.

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6) COMPARISON WITH PREDICATE

The PID-1 has the same intended use as the Victoreen Model 530 Electrometer/ Dosemeter. Both devices allow the operator to measure the charge, charge rate (current), dose (exposure) and dose rate from ionizing radiation beams. These devices are compatible with similar types of radiation probes. The devices are of similar size and weight. Neither device is intended for direct use on patients.

7) SUMMARY OF STUDIES

Tests conducted on calibrated equipment indicate that the PID-1 will measure to the specifications stated in the product literature.

8) CONCLUSIONS

Gammex considers the PID-1 to be substantially equivalent to the Victoreen Model 530 Electrometer/Dosemeter. Comparison of the features indicates that the intended use and effectiveness of the PID-1 do not significantly differ from the predicate device. The PID-1 does not raise any new potential safety risks.